Zimmer Dental

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510k No.: K093164



# Traditional 510(k)
# PRE-MARKET NOTIFICATION 510(k)

## 510(k) SUMMARY (21CFR807.92(a))

DEC 15 2009

1. Submitter's Information:

Name: Zimmer Dental Inc.

Address: 1900 Aston Ave.
Carlsbad, CA 92008

Phone: 760-929-4300

Contact: Melissa Burbage

Date Prepared: December 10, 2009

2. Device Name: 3.25mm *Spline® Twist™* Implant, HA Coated
(cat. No 2130, 2131, 2133, 2135)

Device Classification Name: Endosseous Dental Implant

3. Predicate Device(s):

Predicate Device #1

| | |
|---|---|
| Trade Name: | Integral VI Biointegrated Dental Implant System |
| 510(k) Number: | K944327 |
| Classification: | DZE |
| Classification Name: | Endosseous Dental Implant |
| Classification Panel: | Dental |
| Product Code: | Implants: 1850, 1851, 1852, 1853, 1854, 1870, 1871, 1872, 1873, 1874 |

Predicate Device #2

| | |
|---|---|
| Trade Name: | Small Diameter Spline Twist Implant |
| 510(k) Number: | K012055 |
| Classification: | DZE |

| | |
|---|---|
| Classification Name: | Endosseous Dental Implant |
| Classification Panel: | Dental |
| Product Code: | Implants: No finished good part numbers as the devices were never commercially distributed. |

Predicate Process

| | |
|---|---|
| Trade Name: | Calcitek HA-Coated Endosseous Dental Implants |
| 510(k) Number: | K960021 |
| Classification: | DZE |
| Classification Name: | Endosseous Dental Implant |
| Classification Panel: | Dental |

4. Device Description:

The 3.25mm Spline Twist Implant, HA Coated is a self-tapping, screw type endosseous dental implant design for bone level placement and can be used in a single or two stage protocol. Refer to Figure 1, product renderings. The implant will have a straight body with an external single lead thread design. The new device implant body, fabricated from 6Al-4V titanium alloy, features single lead threads that begin 0.75mm apical of the base of the implant Spline tines and continue to the apex of the implant. The flute are formed by a helical cuts that "twist" or spiral the cutting flutes around the long axis of the implant in the same sense as the threads. The flutes tend to pull the implant into the site and present a positive rake angle to the osteotomy in a manner similar to a spiral flute thread tap. It has a Spline interface that consists of six tines. These tines interdigitate with like tines on abutments used in the system to create an anti-rotation interface. The new device will feature hydroxylapatite (HA) coating , hydroxylapatite coating with additional Zimmer Dental MP-1® processing equivalent to existing Zimmer Dental implants (K953101, K011028, K013227, K061410, K072589).

5. Indications for Use

*Zimmer* Dental Spline implant systems are designed for use in edentulous mandibles or maxillae for attachment of complete denture prostheses for immediate or conventional loading, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a free standing single tooth replacement. The threaded implants should only be immediately loaded when good primary stability is achieved and the functional load is appropriate.

6. Device Comparison:

The new device is substantially equivalent to the predicate devices. The device's, general structure, and function in the endosseous implant system remains the same as the predicate devices.

The 3.25mm Spline Twist Implant, HA Coated is similar in design to the previously cleared Small Diameter Spline Twist Implant. It features a Spline interface that consists of six 0.040 (1mm) tall projections called tines that are arranged circumferentially around a 1-72 unified series, thread tolerance class 3, internal thread. These tines interdigitate with like tines on abutments used on the system to create an anti-rotation interface. A threaded fastener is used to secure the abutment to the implant after assembly.

The body of the 3.25mm Spline Twist Implant, HA Coated is identical to the Small Diameter Spline Twist Implant featuring .1240 (3.15mm) major diameter single lead threads that begin .030" (0.75mm) from the base of the implant Spline tines and continue to the apex of the implant. At a distance of .120" (3.05 mm) coronal from the apex the major diameter of the threads begin to taper inwardly and also is interrupted by three cutting flutes spaced circumferentially at 120 degrees from one another. The flute are formed by a helical cuts that "twist" or spiral the cutting flutes around the long axis of the implant in the same sense as the threads. The flutes tend to pull the implant into the site and present a positive rake angle to the osteotomy in a manner similar to a spiral flute thread tap.

The implant body is fabricated from the same 6AL-4V titanium alloy as the Small Diameter Spline Twist Implant and the Integral VI Biointegrated Dental Implant System. The material is dual specified to *ASTM B328* and *ISO 5832-3*. The ISO specification has stricter controls and material purity and the ASTM has higher limit of minimum strength. The 3.25mm Spline Twist Implant, HA Coated also features the same HA coating as the predicate Integral VI Biointegrated Dental Implant System. The coating is plasma sprayed on to the implant and then processed as the predicate Calcitek HA-Coated Endosseous Dental Implants using a hydro-thermal treatment (MP-1) to increase crystallinity.

The 3.25mm Spline Twist Implant, HA Coated used the same prosthetics as the predicates and these include engaging and not engaging abutments and copings manufactured from titanium alloy, gold alloy and plastic. Plastic is used only a burn out sleeve to create gold copings.

Engaging abutment have tines that interdigitate with the implant tines. A circumferential collar attached to the abutment covers both implant and abutment tines when that abutment is seated. This collar seats on an annular ring on the implant that is positioned outwardly from the implant tines. Non-engaging abutments have a circumferential ring that is integral to the abutment but lack the interdigitating tines. All abutments are held to the implant by a threaded fastener which is either integral to the abutment body or a separate component.

The 3.25mm Spline Twist Implant, HA Coated will use surgical instruments similar to the predicates. A 2.7 mm intermediate drill is being added to the drill sequence and the taps utilized with the predicate Small Diameter Spline Twist Implant are also utilized. The tools used to drive the threaded implant into the osteotomy are also identical to those used on the predicate Small Diameter Spline Twist Implant.

A try-in is provided to check the osteotomy for parallelism and depth. A 2.3mm end can be used after the pilot drill to check angulations and a 3.0mm end is provided for use after the final drill. A band on the 3mm end allows the user to verify the depth of the site prior to surgical placement of the implant.

In the unlikely event that the spline tines are distorted during the surgical procedure, a spline recovery tool is provided to straighten the tines. Tine deformation is unlikely because a tap is provided to pre-thread the site in more dense bone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Melissa Burbage
Manager of Regulatory Affairs
Zimmer Dental, Incorporated
1900 Aston Avenue
Carlsbad, California 92008-7308

DEC 15 2009

Re: K093164
Trade/Device Name: 3.25 Spline® Twist™ Implant, HA Coated
Regulation Number: 21CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: December 10, 2009
Received: December 11, 2009

Dear Ms. Burbage:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# Indications for Use

510(k) Number (if known): K093164

Device Name: *3.25 Spline® Twist™* Implant, HA Coated

Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

R S Betz DDS for Dr. K. P. Mulay (Acting)
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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